

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

THIS DOCUMENT RELATES TO:

All Suits Against the Saint Thomas Entities

MDL No. 2419
Dkt. No 1:13-md-2419 (RWZ)

**SAINT THOMAS ENTITIES' RESPONSE IN OPPOSITION TO PSC'S MOTION TO
COMPEL PRODUCTION OF CERTAIN DOCUMENTS**

The Saint Thomas Entities¹ hereby file their response in opposition to the PSC's motion to compel production of certain documents.² The PSC's motion seeks to compel the production of three categories of documents: (1) various studies and focus group documents related to marketing and branding; (2) all managed care contracts covering St. Thomas Outpatient Neurosurgical Center; and (3) documents showing the inventory of methylprednisolone acetate at all hospitals owned by Saint Thomas Health in 2011 and 2012.³ For the reasons stated below, the PSC's motion to compel should be denied.

I. BACKGROUND

Plaintiffs allege injuries and death based on contaminated epidural injections manufactured and sold by the New England Compounding Center (“NECC”).⁴ Plaintiffs have made claims against numerous health care providers, including the Saint Thomas Entities and St.

¹ Saint Thomas West Hospital f/k/a St. Thomas Hospital; Saint Thomas Health; and Saint Thomas Network.

² Dkt. Nos. 2260, 2261.

³ See Mot. to Compel at 1–2 [Dkt. No. 2260].

⁴ See Mem. of Decision [re: Motions to Dismiss] (Aug. 29, 2014) [Dkt. No. 1360].

Thomas Outpatient Neurosurgical Center (“STOPNC”).⁵ STOPNC purchased contaminated medication from NECC and administered it to patients.⁶ The Saint Thomas Entities include Saint Thomas Health, which is an owner of Saint Thomas Network, which in turn is a co-owner of STOPNC with Howell Allen Clinic.⁷ Plaintiffs assert that STOPNC is the actual or apparent agent of one or more of the Saint Thomas Entities and that the Saint Thomas Entities should be held vicariously liable for STOPNC’s alleged acts or omissions.⁸

Plaintiffs assert that STOPNC and its agents knew or should have known of the dangers of using compounded drugs generally, and specifically, products compounded by NECC.⁹ Plaintiffs allege that STOPNC decided to purchase methylprednisolone acetate (“MPA”) from NECC because it was the cheapest steroid available, and that STOPNC did not conduct appropriate due diligence or investigation into NECC before deciding to purchase and administer NECC-compounded steroids to its patients.¹⁰

II. PROCEDURAL HISTORY

To date, the Saint Thomas Entities have responded to numerous written discovery requests, produced over 36,000 pages of documents, and presented witnesses for ten depositions.¹¹ As relevant here, in August and September 2015, the parties engaged in a meet-and-confer process under Local Rule 37.1 regarding certain alleged deficiencies in the Saint Thomas Entities’ discovery responses. While the parties reached agreement on certain items and

⁵ *Id.* at 2.

⁶ *Id.* at 3.

⁷ *Id.* at 4.

⁸ *Id.*

⁹ *See* Master Compl. ¶¶ 152–58, 180 [Dkt. No. 545]; Mem. in Supp. of Mot. to Compel at 3 [Dkt. No. 2261].

¹⁰ Master Compl. ¶ 192; Mem. in Supp. of Mot. to Compel (“Memo”) at 3.

¹¹ Three of the Saint Thomas Entities’ witnesses were deposed twice, once as fact witnesses and once as Rule 30(b)(6) corporate representatives.

the Saint Thomas Entities agreed to produce some additional documents, the parties were unable to reach agreement on the three categories of documents presently at issue. As explained below, the Plaintiffs seek to compel the production of irrelevant and overly broad information, and their requests are without merit.

III. ARGUMENT

A. Marketing or Brand Surveys are Irrelevant Because They Do Not Concern STOPNC or MPA Injections

Plaintiffs seek several categories of documents related to marketing or branding studies conducted by Saint Thomas Health and/or St. Thomas Hospital:

- “Brand attribute surveys” (Request for Production (“RFP”) No. 51);
- Annual surveys (RFP No. 52);
- Transcripts of focus groups (RFP No. 53);
- Focus group summaries prepared by Tombras (RFP No. 54);
- All documents related to any focus group conducted by Saint Thomas Health and/or St. Thomas Hospital (RFP No. 58).¹²

The PSC argues that that these documents are relevant to its claim that STOPNC was the actual or apparent agent of one or more of the Saint Thomas Entities. The evidence in question concerns surveys and focus groups on the reputation of Saint Thomas Hospital and Saint Thomas Health. The PSC appears to believe that evidence on how highly regarded or recognizable Saint Thomas Hospital and Saint Thomas Health are in the Nashville metropolitan area is relevant to their agency claim. To assess the PSC’s relevancy argument, one needs to understand the elements required to establish actual or apparent agency under Tennessee law.

Actual agency requires consideration of at least the following elements:

¹² Memo at 8–10 (quoting Saint Thomas Health’s Objections and Responses to certain requests for production).

- 1) Whether the alleged principal had the right to control the acts of the agent¹³; and
- 2) The amount of control by the principal over the “means and method” of the work of the agent.¹⁴

In contrast, apparent agency requires at least the following:

- (1) That the principal ***held the agent out to the public*** as possessing ***sufficient authority*** to ***embrace the particular act in question***, or knowingly permitted him to act as having such authority; and
- (2) that the [plaintiff] ***knew of the facts***, and, acting in good faith, had reason to believe, and did believe, that the agent possessed the necessary authority.¹⁵

Cases have further explained that the second factor of apparent agency requires the plaintiff to have “relied on [the alleged] apparent authority to his or her detriment.”¹⁶ For example, in the context of holding a hospital responsible for a doctor’s medical negligence under an apparent agency theory, the law requires that the plaintiff “looked to the hospital rather than to the individual physician” to perform the services.¹⁷

With respect to marketing or branding surveys and focus groups, such information has no bearing on whether the Saint Thomas Entities had the right to control or exerted control over STOPNC. The PSC makes no meaningful attempt to argue to the contrary.

With respect to apparent agency, the discovery likewise is irrelevant. Replacing the facts of this case into the factors cited, the legal analysis becomes:

- (1) Did Saint Thomas Health, Saint Thomas Network, and/or St. Thomas Hospital hold STOPNC out to the public as possessing authority to administer surgical procedures (i.e., epidural steroid injections) on their behalves?;

¹³ See *Johnson v. LeBonheur Children’s Med. Ctr.*, 74 S.W.3d 338, 343 (Tenn. 2002) (citation omitted).

¹⁴ *Davis v. University Physicians Found., Inc.*, No. 02A01-9812-CV-00346, 1999 WL 643388, at *4 (Tenn. Ct. App. Aug. 24, 1999) (quoting *McDonald v. Dunn Constr. Co.*, 185 S.W.2d 517, 520 (Tenn. 1945)).

¹⁵ *Southern Ry. Co. v. Pickle*, 138 Tenn. 238, 246 (Tenn. 1917) (emphasis added).

¹⁶ *Id.* at 433 (quoting *Mechs. Laundry Serv. v. Auto Glass Co. of Memphis*, 98 S.W.3d 151, 157 (Tenn. Ct. App. 2002)).

¹⁷ *Boren ex rel. Boren v. Weeks*, 251 S.W.3d 426, 436 (Tenn. 2008).

2) Did each plaintiff know that Saint Thomas Health, Saint Thomas Network, and/or St. Thomas Hospital held STOPNC out to the public as possessing authority to administer surgical procedures on their behalves?; and

3) Did each plaintiff look to one of the Saint Thomas Entities rather than STOPNC for surgical procedures?

Put in this context, the PSC's request is overly broad and seeks information that is completely irrelevant. First, as the requests are worded, they could cover surveys the hospital did on whether St. Thomas Hospital patients liked the food they ate as an inpatient, whether hospital staff was knowledgeable, patient satisfaction surveys, etc. None of this has anything to do with this lawsuit. Similarly, to the extent the hospital or Saint Thomas Health conducted a focus group has nothing to do with the required showing that one of the Saint Thomas Entities held STOPNC out (or permitted STOPNC to act) as possessing authority to provide MPA treatments on its behalf.

Even if these requests were limited to "brand" surveys or focus groups, the documents remain irrelevant. Once again, whether "the public" believed St. Thomas Hospital provided high or low quality services has no bearing on this case. Similarly, by definition, a survey or focus group is an accumulation (and usually averaging) of public opinion on a company or issue. The elements of apparent agency under Tennessee law requires a plaintiff to have relied on a representation of an alleged principal. Focus groups and surveys are private, internal business development tools. By definition no Plaintiff could have relied on any of these materials.

Noticeably absent from the PSC's motion to compel is any evidence *from any Plaintiff* to support the relevancy of a focus group or brand survey. For example, the PSC would at least have a good faith argument for production of a survey *submitted by one their Plaintiff clients*. Yet apparently none of their clients participated in any surveys or focus groups, hence no such evidence was submitted.

And by definition, a survey or focus group asks questions to elicit responses from the participants. The PSC fails to explain how *somebody else's answer or belief* to any possible question that was posed by the hospital or Saint Thomas Health has any bearing on what a Plaintiff in this proceeding observed and relied upon in seeking MPA treatment. And most importantly, none of the Saint Thomas Entities ever held any focus groups or surveys regarding STOPNC or the administration of MPA. *See* Declaration of Rebecca Climer at ¶ 3, attached hereto as Exhibit A. Unlike the PSC, the Saint Thomas Entities are providing proof in support of their response.

In addition, STOPNC was formed in 2000 and has been named “St. Thomas Outpatient Neurosurgical Center” since its formation,¹⁸ meaning the decision to include “St. Thomas” in STOPNC’s name must have been made in or before 2000. Therefore, documents related to any brand surveys or focus groups conducted in 2012 or the years leading up to 2012 are completely irrelevant. And as noted in the Saint Thomas Entities’ August 21, 2015 response to the PSC’s Meet-and-Confer Letter, no responsive documents prior to the formation of STOPNC have been located.

Without any survey questions or focus groups questions concerning STOPNC or the administration of MPA, the PSC’s shotgun request for all survey and focus groups conducted by Saint Thomas Health or St. Thomas Hospital should be denied.

B. The “One Name, One Healing Community” Hospital Advertising Campaign is Irrelevant Because It Concerns Hospitals and Occurred After the Outbreak

The PSC next moves to compel the following:

¹⁸ See Transcript Excerpt at 14:8; 23:12–21, Feb. 5, 2015 Deposition of S. Butler, attached hereto as Exhibit B.

- All documents “relied upon by Saint Thomas Health and/or Saint Thomas in development of the ‘One Name[,] One Healing Community’ advertising campaign” (RFP No. 57).

This request concerns that fact that *in 2013*, after the meningitis outbreak at issue in this litigation, Saint Thomas Health decided to rename all of the hospitals it owned to include “Saint Thomas” in their names. To inform the public that the hospitals had been renamed, Saint Thomas Health created a marketing campaign that used the phrase “One Name, One Healing Community.” Importantly, as the picture the PSC inserted in its motion proves, the ads and billboards at issue listed the five hospitals that were being renamed (Defendant St. Thomas Hospital was renamed Saint Thomas West Hospital). The campaign had nothing to do with STOPNC.

Putting aside the fact that the marketing campaign had to do with hospitals, it is irrelevant to this litigation because no Plaintiff could possibly have seen or relied on the ads given the fact the campaign did not occur until *after* the meningitis outbreak. And as noted above, relevant evidence must have been relied upon by a Plaintiff, which could not have happened with respect to this campaign. Stated differently, it is *impossible* for this marketing campaign to have had any effect on any Plaintiff’s decision to seek medical treatment from STOPNC in 2012.

The reason the PSC is grasping at straws here is because none of the Saint Thomas Entities *ever advertised* STOPNC or STOPNC’s services. What the PSC needs in order to submit a legitimate apparent agency issue to a jury is an ad campaign instituted by Saint Thomas Health, St. Thomas Hospital, or Saint Thomas Network, seen by a Plaintiff, that said something along the lines of “Pain Relief Today: Get your next MPA treatment at St. Thomas Hospital,” with that Plaintiff having relied on the advertisement and gone to St. Thomas Hospital for the injection, but with a hospital employee having taken them to STOPNC for the injection instead of the hospital.

This of course never happened because no Saint Thomas Entity ever “held itself out” in this manner and accordingly no Plaintiff ever relied to his or her detriment in such a way. Similarly, no Plaintiff ever relied on marketing materials to obtain services at STOPNC because *every* patient who received services at STOPNC *was referred by a Howell Allen Clinic doctor*.¹⁹ Indeed, as the President of Howell Allen Clinic and Chairman of the STOPNC Board testified, no patient could obtain services at STOPNC without being referred there by a Howell Allen Clinic doctor.²⁰ With discovery *having turned up nothing*, the PSC instead seeks to compel materials their clients never saw, never could have seen, and accordingly never relied on.

C. Managed Care Agreements Are Irrelevant Because Surgical Procedures are Paid at a Single Fee Per Medicare Regulations

Like nearly every health care provider in the country, STOPNC has managed care contracts with numerous insurance companies. The insurance companies negotiate the payment they will make to STOPNC when one of their policyholders obtains medical services there. Saint Thomas Health contracted with STOPNC to negotiate many of these contracts with insurers, a service that Saint Thomas Health provided to its joint ventures in exchange for compensation. Accordingly, Saint Thomas Health included addenda or attachments to the managed care contracts it negotiated on behalf of the hospitals owned by it to include payment terms and rate schedules.

The PSC requested “all contracts, agreements, and documents related to Saint Thomas Health’s relationship with STOPNC.”²¹ Subject to objections, Saint Thomas Health produced an exemplar managed care contract with Blue Cross Blue Shield.

¹⁹ Transcript Excerpt at 69:1–4, Sept. 18, 2015 Deposition of G. Lanford, attached hereto as Exhibit C.

²⁰ *Id.*

²¹ Memo at 11.

The PSC now seeks a copy of every managed care contract that covers STOPNC on two grounds: 1) the agreements show that the health insurers were reimbursing for drug costs²²; and 2) the agreements show that the insurance companies did not pay for drugs like MPA separately from the injection. As to the latter point, the PSC argues that because STOPNC received a single fee for each procedure, it had the incentive to pay as little as possible for drugs it purchased. In context, neither of these relevancy claims support production of all managed care contracts.

To understand why the PSC's relevancy claims are groundless, one needs to understand how Medicare and health insurers pay for the procedures done at STOPNC that are at issue in the MDL. STOPNC is an ambulatory surgical center ("ASC") and accordingly Medicare pays a single fee for such procedures.²³ As the ASC fee schedule explains:

*Medicare makes a single payment to ASCs for covered surgical procedures, including ASC facility services furnished in connection with the covered procedure. Examples of covered ASC facility services paid through the payment for covered surgical procedures include . . . Drugs . . .*²⁴

In other words, regardless of which drugs STOPNC uses, where it purchases drugs from, or how much it pays for the drugs it uses, STOPNC receives the same reimbursement from Medicare. As STOPNC has admitted in its interrogatory responses, reimbursements for all health insurers are submitted and thus paid *the same way*.²⁵ In other words, reimbursements for STOPNC are done the same way whether Medicare or a private health insurer is paying, the only difference being the amount reimbursed.

²² The PSC's brief says that the Blue Cross Blue Shield managed care agreement states that its payments to STOPNC includes "a sale of 'drugs.'" Memo at 12. The agreement says no such thing. It says the reimbursement rate "includes laser, equipment, drugs and facility charges." See July 29, 2015 Deposition of C. Williams, Ex. 517 at 6, attached hereto as Exhibit D. This is undisputed and consistent with how Medicare works, as discussed *supra*.

²³ The government has assigned such procedure HCPCS Code 62311, as reflected on the billing screen shot submitted by STOPNC in its interrogatory responses. See STOPNC's First Supplemental Responses to the PSC's First Set of Interrogatories at 8-9, attached hereto as Exhibit E.

²⁴ Centers for Medicare & Medicaid Services, *Ambulatory Surgical Center Fee Schedule, Payment System Fact Sheet Series* (Dec. 2011), excerpt attached hereto as Exhibit F (emphasis added).

²⁵ See Ex. E at 2-3.

For the PSC to argue that it needs a copy of every managed care contract to see how STOPNC was being reimbursed for surgical procedures is disingenuous. First, the PSC has admitted in its own interrogatory responses that the manner described above is how STOPNC likely gets paid for procedures.²⁶ Second, each Plaintiff would have received an Explanation of Benefits (“EOB”) from the particular health insurer it used that confirmed this was how the surgical procedure was reimbursed, and the Plaintiffs certainly have access to their own EOBs. Third, STOPNC itself has been clear that this is how it bills all health insurers. Fourth, the Saint Thomas Entities produced an exemplar managed care contract to demonstrate they provide no additional information. Finally, the PSC has deposed numerous witnesses from STOPNC (including a corporate representative) at which it was able to ask any question it wanted regarding health insurance reimbursements. Indeed, it actually obtained testimony on the undisputed (and undisputable) point that under this payment system, STOPNC profited by minimizing expenses (hardly a novel point in any business).²⁷

Because the manner of payment for the procedures at issue was done in accordance with Medicare regulations, there is no dispute in this MDL proceeding that the single payment made for the procedure included compensation for any drugs used during the course of providing this treatment. STOPNC has produced documents reflecting how much it was actually reimbursed for every Plaintiff in the MDL. The contents of the managed care agreements are irrelevant. The PSC’s request is nothing but a prohibited fishing expedition.

²⁶ See PSC’s Second Supplemental Response to [Nashville Clinic Defendants’] First Interrogatories and Requests for Production of Documents at 2–3, excerpt attached hereto as Exhibit G.

²⁷ Tr. at 61:8–15; Transcript Excerpt at 117:5–13, Mar. 23, 2015 Deposition of J. Culclasure, attached hereto as Exhibit H.

D. The Stock of MPA at Other Hospitals is Irrelevant

The PSC's Second Set of Requests for Production sought documents regarding the inventory of MPA at St. Thomas Hospital and Saint Thomas Health in 2011 and 2012.²⁸ No responsive documents were located.²⁹ The PSC now seeks to compel any such documents from four other hospitals directly or indirectly owned by Saint Thomas Health in 2012.³⁰ Plaintiffs' request should be denied.

The four hospitals at issue—Saint Thomas Midtown, Saint Thomas Hickman, Saint Thomas Rutherford, and Saint Thomas Hospital for Specialty Surgery—are separate entities and are not, nor have they ever been, parties to this litigation. They have no connection to the meningitis outbreak and no Plaintiff received any relevant services from any of them.

The supply of MPA in 2012 at these four hospitals, if any, has no relevance to the claims and defenses at issue in this litigation. The evidence is uncontroverted that in 2012, two manufacturers of generic MPA had put the drug on backorder, which was driving up prices.³¹ Debra Schamberg has testified that accordingly, she began looking for a different supplier of MPA.³² STOPNC has never claimed that it ran out of MPA and was forced to buy from NECC. It has never claimed that health care providers in Nashville were short on or out of the drug. Instead, it said MPA was backordered and that based on increased demand (and thus prices) from

²⁸ RFP Nos. 63, 64, Saint Thomas Health's Objections and Responses to PSC's Second Set of Requests for Production, excerpt attached hereto as Exhibit I; RFP Nos. 63, 64, St. Thomas Hospital's Objections and Responses to PSC's Second Set of Requests for Production, attached hereto as Exhibit J.

²⁹ Ex. I at 3 (RFP No. 63); Ex. J at 3 (RFP Nos. 63, 64). Saint Thomas Health stood on its objections with respect to RFP No. 64, which broadened the request to include the phrase "and its affiliates, subsidiaries, joint ventures, and/or related entities" in parentheses after "Saint Thomas Health." Ex. I at 4.

³⁰ Memo at 13.

³¹ See, e.g., Daniel Weiss, *Meningitis Outbreak Linked to Drug Shortages*, Pharmacy Times (Nov. 12, 2012), available at <http://www.pharmacytimes.com/news/meningitis-outbreak-linked-to-drug-shortages> (last accessed Oct. 5, 2015).

³² Transcript Excerpt at 85:7–18, Feb. 4, 2015 Deposition of D. Schamberg, attached hereto as Exhibit K.

a shorter supply, it was concerned about being able to obtain a consistent supply in the future.³³ The supply of MPA at nearby hospitals in 2011 and 2012 is completely irrelevant.

Moreover, the PSC already deposed the corporate representative of Clint Pharmaceuticals Inc., the pharmaceutical supplier that supplied MPA to STOPNC for part of 2011, to address what was and was not available for sale in 2011 and 2012. It is undisputed that Saint Thomas Health or the hospitals owned by it did not sell or provide supplies or medications to STOPNC.³⁴ Therefore, the supply of MPA at hospitals owned by Saint Thomas Health in 2011 and 2012 is entirely irrelevant because whether such hospitals possessed one vial of MPA or 10,000, STOPNC did not have access to it. The discovery request should be denied.

IV. CONCLUSION

WHEREFORE, the Saint Thomas Entities respectfully request that the Court deny the PSC's motion to compel.

³³ *Id.* at 86:5–10.

³⁴ *See, e.g.*, Transcript Excerpt at 105:19–106:11, Aug. 21, 2015 Deposition of C. Leffler, attached hereto as Exhibit L

Dated: October 5, 2015

SAINT THOMAS WEST HOSPITAL F/K/A
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CERTIFICATE OF SERVICE

I certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing this 5th day of October, 2015.

/s/ Sarah Kelly

Sarah P. Kelly